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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,130	01/20/2004	Michael Smith	117622-00105	6639
27557	7590	05/04/2006	EXAMINER	
BLANK ROME LLP 600 NEW HAMPSHIRE AVENUE, N.W. WASHINGTON, DC 20037			TOTH, KAREN E	
			ART UNIT	PAPER NUMBER
			3735	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/759,130

Applicant(s)

SMITH ET AL.

Examiner

Karen E. Toth

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2 March 2005.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: Paragraph [0005] defines peripheral pulse volume as having units of microliters per centimeter of limb length. Since the generally accepted unit "volume" does not contain units of length, it is suggested that, throughout the application, the term "peripheral pulse volume" be changed to --peripheral pulse volume per length--, or a similar phrase, in order to accurately reflect what is being measured.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4-7 and 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 19 disclose the calculation of a pulsatile flow as the product of pulse volume and heart rate. It is not clear exactly what is being measured, as specific units are not provided. Additionally, it is known in the art to calculate cardiac output, the amount of blood produced by the heart, as the product of stroke volume and heart rate, as taught by Romano (US Patent 6758822) and Muhlenberg (US Patent 7024244). It is not clear how the disclosed measurement of pulsatile flow differs from or is related to

cardiac output, since they are found by the same type of calculation but produce different results.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 9-13, 16, and 24-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Raines'587 (US Patent 6149587).

Regarding Claim 1, Raines'587 discloses a method of measuring peripheral vascular function comprising measuring the peripheral pulse volume of a subject (column 6, lines 31-36); measuring the blood pressure of the subject (column 6, lines 60-62); and calculating a representation of the patient's vascular function based upon the measured pulse volume and blood pressure (see "Ankle/Arm Index" in Figure 16).

Regarding Claim 9, Raines'587 further discloses using a display monitor to display the results of testing, measurements, and analysis (column 3, lines 11-14).

Regarding Claim 10, Raines'587 further discloses using a storage device to store patient data for later review (column 17, lines 39-41).

Regarding Claim 11, Raines'587 further discloses using a communication link (element 14) to transmit data to a remote device (element 12; Figure 1).

Regarding Claim 12, Raines'587 further discloses performing said method using a device which integrates all the components (element 10; Figure 1).

Regarding Claim 13, Raines'587 further discloses that pulse volume measurements are taken using a pulse volume recorder (column 11, lines 6-7); that blood pressure measurements are taken using a plethysmograph; that computing steps are performed using examination and analyzing units; and that said devices are linked only electronically (column 2, line 66 to column 3, line 1).

Regarding Claim 14, Raines'587 further discloses that the data signals generated by physiological measurements are automatically sent to the computing unit (column 3, lines 4-6).

Regarding Claim 15, Raines'587 further discloses that vascular testing data such as blood pressure and other tests may be manually input to the computer system (column 16, lines 58-64).

Regarding Claim 16, Raines'587 discloses a system for measuring peripheral vascular function comprising a pulse volume measurement device (column 6, lines 31-36); a blood pressure measurement device (column 6, lines 60-62); and a computing unit (elements 12 and 16) that is used to calculate a representation of the patient's vascular function based upon the measured pulse volume and blood pressure (column 21, lines 58-59; see "Ankle/Arm Index" in Figure 16).

Regarding Claim 24, Raines'587 further discloses that the system comprises a display device (element 17) that is used to display the results of testing, measurements, and analysis (column 3, lines 11-14).

Regarding Claim 25, Raines'587 further discloses that the computing component of the system comprises a storage device that is used to store patient data for later review (column 17, lines 39-41).

Regarding Claim 26, Raines'587 further discloses that the system comprises a communication link (element 14) that is used to transmit the patient data to a remote location for review (element 12; Figure 1).

Regarding Claim 27, Raines'587 further discloses that the system components are contained within an integrated device (column 2, line 66 to column 3, line 1).

Regarding Claim 28, Raines'587 further discloses that the system components are provided separately (column 2, line 66 to column 3, line 1).

Regarding Claim 29, Raines'587 further discloses that the system components electronically communicate and automatically transfer data (column 3, lines 4-7).

Regarding Claim 30, Raines'587 further discloses that the a manual input device (element 140) maybe used to enter data such as blood pressure and other vascular testing results (column 16, lines 58-64).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 2, 3, 8, 17, 18, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raines'587 in view of Chio'130 (US Patent 6165130).

Regarding Claim 2, Raines'587 discloses all the elements of the current invention, as applied to Claim 1 above, except for the method comprising measuring the patient's systolic and diastolic blood pressures, and using the measurements to calculate the patient's pulse pressure. Raines'587 further discloses measuring the patient's systolic blood pressure (column 6, lines 60-62), but does not disclose measuring diastolic blood pressure.

Chio'130 teaches a method of cardiac monitoring comprising measuring both the systolic and diastolic blood pressures of a patient (column 18, lines 19-21 and 33-36), and using the blood pressure measurements to calculate the patient's pulse pressure (column 6, lines 57-58), in order to provide a more complete analysis of the patient's cardiac condition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have performed the method of Raines'587 and further measured systolic and diastolic blood pressure for use in calculating pulse pressure, as taught by

Chio'130, in order to provide a more complete analysis of the patient's cardiac condition.

Regarding Claim 3, Raines'587 further discloses measuring the patient's pulse as part of the cardiac evaluation method (column 33, lines 57-60; Figure 36).

Regarding Claim 8, Raines'587 in view of Chio'130 discloses all the elements of the current invention, as applied to claim 2 above, except for the step of calculating vascular compliance as pulse volume divided by pulse pressure.

Chio'130 further discloses calculating the compliance of a vessel as the change in vessel volume divided by the change in vessel pressure (equation 2; column 8, line 66; column 9, lines 4 and 11-12) in order to evaluate a subject's hypertension.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have performed the measurements of Raines'587 in view of Chio'130, with the additional step of calculating the compliance of a vessel, as taught by Chio'130, in order to evaluate a subject's hypertension.

Regarding Claim 17, Raines'587 discloses all the elements of the current invention, as applied to Claim 16 above, except for the blood pressure measuring device measuring the systolic and diastolic blood pressures of the patient and using the blood pressure measurements to calculate the patient's pulse pressure. Raines'587 further discloses using the blood pressure measuring device to measure the patient's systolic blood pressure (column 6, lines 60-62), but does not disclose measuring diastolic blood pressure.

Chio'130 teaches a system for cardiac monitoring comprising using a blood pressure measuring device to measure both the systolic and diastolic blood pressures of a patient (column 18, lines 19-21 and 33-36), and using the blood pressure measurements to calculate the patient's pulse pressure (column 6, lines 57-58), in order to provide a more complete analysis of the patient's cardiac condition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed the system of Raines'587 with the additional ability to capture systolic and diastolic blood pressure measurements and use the measurements to calculate the patient's pulse pressure, as taught by Chio'130, in order to provide a more complete analysis of the patient's cardiac condition.

Regarding Claim 18, Raines'587 further teaches using the patient's pulse as part of one of the system components of the patient's cardiac evaluation (column 33, lines 57-60; Figure 36).

Regarding Claim 23, Raines'587 in view of Chio'130 discloses all the elements of the current invention, as applied to claim 17 above, except for the system calculating the compliance of a vessel as pulse volume divided by pulse pressure.

Chio'130 further teaches that the system calculates the compliance of a vessel as the change in vessel volume divided by the change in vessel pressure (equation 2; column 8, line 66; column 9, lines 4 and 11-12) in order to evaluate a subject's hypertension.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed the system of Raines'587 in view of Chio'130, with

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the additional ability to calculate the compliance of a vessel, as taught by Chio'130, in order to evaluate a subject's hypertension.

Allowable Subject Matter

9. Claims 4-7 and 19-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 4112491 to Bugay, which discloses pulsatile flow measurement and calculation.

US Patent 4569355 to Bitterly, which discloses a peripheral blood flow monitoring method and apparatus

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Robert S. Mason
ROBERT S. MASON
PATENT ATTORNEY